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EXAMINER

CHISM, BILLY D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/817,725

Applicant(s)

KINSTLER ET AL.

Examiner

B. Dell Chism

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 50-53 is/are pending in the application.
- 4a) Of the above claim(s) 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50 and 51 is/are rejected.
- 7) ☒ Claim(s) 52 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date 5-24-01; 6-24-02. | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 50-52, in the reply filed on 17 February 2005 is acknowledged. Claims 50-53 are pending with claim 53 withdrawn from consideration as non-elected subject matter.

#### *Claim Objections*

2. Claim 52 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

#### *Double Patenting*

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 50-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 5,985,265 ('265).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the '265 patent teaches a species of the instantly claimed invention. Claims 2-6 of '265 are drawn to methods of making a substantially homogenous preparation of a N-terminally

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monoPEGylated consensus interferon, as is in claim 4, that is essentially free of PEGylation at sites other than the N-terminus and wherein the claimed consensus interferon is a protein that is PEGylated and has a molecular weight of about 2 kDa to about 100 kDa, thus meeting all the limitations of the genus claimed in the instant claims 50-51. Since it is considered that a species anticipates a genus, then the substantially homogenous N-terminus monoPEGylated consensus interferon '265 patent anticipates the general genus of substantially homogenous N-terminus monoPEGylated protein of the instant application.

It should also be noted that there is no terminal disclaimer between the instant application and the '265 patent.

5. Claims 50-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 63-77 of copending Application No. 10/264,846 ('846) in view of U.S. Patent No. 5,985,265 ('265) (cited above). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 63 of '846 teaches an N-terminally monoPEGylated consensus interferon. Claims 63-77 of '846 are interpreted to be in a pure form (see claim 65 which recites "essentially free"), thus, meeting the limitation of "substantially homogenous" of the instant claim 50. Additionally, claim 63-65 of '846 is not limited to the molecular weight of 2 kDa to about 100 kDa, however, as is discussed in the above Patent No. 5,985,265 ('265), N-terminally monoPEGylated consensus interferon is within the molecular weight range of 2 kDa to about 100 kDa (see claim 3)(note '846 and '265 patent claim N-terminally monoPEGylated consensus interferons. Therefor it would have been obvious to chose the molecular weight range of between 2kDA and

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100 kDA because the '265 patent claims this molecular weight range as an effective pharmaceutical. Also, the pharmaceutical composition of claim 77 of '846 is to a N-terminally monoPEGylated consensus interferon renders obvious the instantly claimed genus of claims 50-51. Again, since the product claimed in the '846 application is a species of the substantially homogenous N-terminus monoPEGylated protein of instant claims 50-51, and since the species renders obvious the genus, then the instantly claimed proteins and pharmaceutical compositions would be obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented; however, the '846 application is currently awaiting issuance of a Patent Number. Once the '846 application is issued this provisional obviousness-type double patenting rejection will become a non-provisional rejection.

6. Claims 50-51 are directed to an invention not patentably distinct from claims 63 of commonly assigned US Patent Application 10/264,846. Specifically, see the discussion and reasons set forth in the rejection of Claims 50-51, provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 63-77 of copending Application No. 10/264,846 ('846) in view of U.S. Patent No. 5,985,265 ('265) (cited above).

The U.S. Patent and Trademark Office normally will not institute interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned 10/264,846 ('846), discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at

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the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

7. Claims 50-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1, 4 and 13-14 of U.S. Patent No. 5,770,577 ('577). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 13 teaches a substantially homogenous preparation of N-terminally monoPEGylated BDNF, that in light of claims 1 and 4, it is taught that the N-terminally monoPEGylated BDNF has a molecular weight of about 2 kDa to about 100 kDa. Claim 14 claims a pharmaceutical composition comprising monoPEGylated BDNF. Thus, since BDNF is a species of the genus of proteins, with a molecular weight of about 2 kDa to about 100 kDa as N-terminally monoPEGylated, then one could envisage the substantially homogenous preparation of N-terminally monoPEGylated BDNF being a species that anticipates the genus of substantially homogenous preparation of N-terminally monoPEGylated proteins as are currently claimed in claims 50-51.

Claims 50-51 are directed to an invention not patentably distinct from claims 1, 4 and 13-14 of commonly assigned U.S. Patent No. 5,770,577 ('577). Specifically, as set forth in the

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rejection of Claims 50-51, rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1, 4 and 13-14 of U.S. Patent No. 5,770,577 ('577).

The U.S. Patent and Trademark Office normally will not institute interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned U.S. Patent No. 5,770,577 ('577), discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

8. Claims 50-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-2 and 5-6 of U.S. Patent No. 5,795,569 ('569). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 claims a polypeptide consisting of amino acids 1-163 of SEQ ID NO: 25, wherein a single polyethylene glycol is attached to the .alpha.-amino group at the N-terminus of said polypeptide, also taught in claim 5 as a substantially homogenous preparation. Note,

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claim 2 claims a polypeptide according to claim 1, wherein said polyethylene glycol has an average molecular weight of 5 kDa to 50 kDa. Claim 6 a pharmaceutical composition comprising the monoPEGylated polypeptide. Since claim 1 of the US Patent is a species of what is instantly claimed in claims 50-51, with a molecular weight of about 5 kDa to about 100 kDa as N-terminally monoPEGylated, then one could envisage the substantially homogenous preparation of N-terminally monoPEGylated polypeptide of SEQ ID NO: 25 being a species that anticipates the genus of substantially homogenous preparation of N-terminally monoPEGylated proteins as are currently claimed in claims 50-51.

9. Claims 50-51 are directed to an invention not patentably distinct from claims 1-2 and 5-6 of U.S. Patent No. 5,795,569 ('569). Specifically, as set forth in the rejection of Claims 50-51, rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-2 and 5-6 of U.S. Patent No. 5,795,569 ('569).

The U.S. Patent and Trademark Office normally will not institute interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Patent No. 5,795,569 ('569), discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.



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A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 50-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Karasiewicz et al. (US Patent 5,382,657). Karasiewicz et al. teach a monoPEGylated interferon with a glycol molecular weight of between 300 Da (or 3 kDa) to about 10,000 Da (or 10 kDa)(see column 2, line 59 through column 4, line 36), and wherein the PEGylated interferon was purified (column 10, lines 2-6 and column 10, lines 43-45). The teachings of Karasiewicz et al. anticipate the instantly claimed genus of substantially homogenous, N-terminally monoPEGylated proteins with a molecular weight of from 2 kDa to about 100 kDa. Since a species always anticipated a genus (MPEP sect. 2131.02), and since Karasiewicz et al. teach a species (interferon) of the instantly claimed genus (protein), one could clearly envisage a genus comprising a N-terminally, monoPEGylated protein given the species disclosed in Karasiewicz et al.

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***Information Disclosure Statement***

12. References B26 and B34-B40 were not considered because they lacked translations.
13. References C24 and C26 were not considered because they were not included in the IDS.

***Conclusion***

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism, whose telephone number is (571) 272-0962. The examiner can normally be reached on M-F 08:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on (571) 272-0974.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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B. Dell Chism

**PATENT EXAMINER**

